GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4874
ANSWERED ON:16.12.2016
Clinical Research Hub
Karandlaje Km. Shobha

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government plans to adopt global practices on clinical trials and coagulate funds for research and development expenditure in pharmaceuticals;

(b) if so, the details thereof;

(c) whether the Government proposes to reduce processing and approval timeline while at same time ensure quality parameters in order to create clinical research hub in the country, if so, the details thereof; and

(d) the details of the cities identified for proposed clinical research hubs in the country?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a) to (c): The Government has taken a series of measures to harmonise regulations for conduct of clinical trials with international practices and for ensuring robustness of the entire process of approvals. Through these measures, the processes related to grant of approval for clinical trials, including bringing higher degree of clarity in the rules, increase in the number of Subject Experts, and online receipt, processing and approval of clinical trial related applications has been rationalised. Further, the Clinical Trial sites are inspected for conformity with Good Clinical Practices, and provisions including for payment of compensation have been made for ensuring patient safety and welfare.
(d): No city have been identified as the clinical research hub in the country.
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